Evidence, resources and an open formulary for the state sector

The drive towards evidence based approaches in medicine, is designed to inform clinical practice. To this end, there are journals (generally not open access, e.g. Evidence Based Mental Health) and internet sites dedicated to informing mental health care practitioners of evidence on a range of issues related to clinical practice, including prescribing. This is certainly to be welcomed insofar as both clinicians and patients might feel more comfortable with treatment decisions. Alternatively, clinicians might feel hamstrung by virtue of evidence that appears to compel them to practice in a way that they are not personally familiar, or comfortable, with based on how they were either taught or how they practice. In an age of increasing consumer advocacy, ''evidence'' may serve as a source of demand. Whilst one cannot seemingly argue with the ''evidence'', it does become problematic when what is understood to be a sound treatment option is unaffordable. This is where the demand of ''evidence'' meets the constraint of ''resource''. There is no question that resource constraints are a reality in the developing world and South Africa is certainly, at this point in her history, a developing nation. Yet there are parallel systems in South Africa whereby those of means and those without exist side by side, where resources are not an issue for some, but a harsh reality for most. What does the ''evidence'' tell us in such a situation where resources constrain the implementation of approaches suggested by the evidence (which is especially found in the state sector)? Are our patients receiving less than they should and if so, is this acceptable practice? Clinicians might be rightfully concerned and frustrated in this regard. Whilst the burden of provision does appear as primarily a clinician responsibility, this requires some critical reflection. In an earlier editorial of this Journal the issue of the Mental Health Care Act was addressed[1]; specifically with respect to the delivery of new legislation, with the expectation of service delivery in line with the provisions of the Act, without apparent costing and adequate resource allocation to facilitate adequate implementation. In this instance, the responsibility lies with government. However, to hold government accountable requires appropriate and coordinated action from those deemed responsible for implementation in the clinical situation as well as from those receiving care. Accepting this to be the case, the role of patients, their families, as well as the emerging consumer advocacy groups become partners in such an alliance. In psychiatry this is more easily said than done given the unique context in which the doctor-patient relationship often unfolds.

The role of second generation antipsychotics (SGAs) in the treatment of schizophrenia is being increasingly – albeit inconsistently - promoted, through various guidelines and algorithms, as a first line intervention in the treatment of schizophrenia; this by way of ''evidence'' demonstrating equivalent efficacy and fewer side effects compared to the first generation antipsychotics (FGAs).[2] More recently, there has been talk of 'third generation' antispsychotics in the form of dopamine-serotonin system stabilizers.[3] For all the brou'haha surrounding the relative absence of SGAs in the state sector, the Department of Health's Essential Drug List (EDL) maintained the status quo without any knowledge, during the expert review panel deliberations , of the impending CATIE or CUtLASS 1 studies.[4,5] Both of these studies stand out in challenging, and potentially dispelling, notions of clear cut superiority of SGAs over FGAs. In fact these studies have, in terms of their methodological differences from the standard industry sponsored randomized, double blind, placebo controlled trials, brought into sharp focus the difference between the clinical trial setting and that of the real world practice of daily clinical psychiatry. From a state sector perspective, the findings of these studies would appear to vindicate a more cost driven approach that questioned the need for an array of SGAs. From an industry perspective the latest studies serve as something of a cautionary in terms of the vulnerability of, apparently glowing, clinical trial data for the SGAs which follows on the more recent documentation of metabolic side effects as cause for concern in this class of drugs. So where does this leave the clinician ? Quite frankly in no different a position to where they were before the CATIE and CUtLASS 1 studies insofar as the SGAs have not been discredited.[4,5] At worst they have potentially been removed from their apparently unassailable lofty perch from where they were able to laud it over the FGAs. It would be folly to turn on the SGAs, whose emergence certainly added to the existing pharmacopoeia. The reality is that whilst these are indeed effective drugs their utility appears narrower than industry might have led us to believe and with the potential for side effects that require clinicians to exercise caution and vigilance when prescribing these agents. Beyond the issues of efficacy, effectiveness, quality of life and financial cost, the evidence in terms of currently available medications for the treatment of schizophrenia appears to be telling us that we still have some way to go in terms of optimal pharmacological interventions.[6] This is clearly a future goal.

Given the aforementioned is it reasonable for clinicians in the state sector to continue to push for a more open formulary with regard not only to SGAs but all agents? Clinical experience has shown that there are patient specific responses to agents and on this basis the widest range of treatment options should be available. That being achieved, it would place an obligation on clinicians to prescribe judiciously, taking all the 'evidence' into account. Whilst the requirement of providing comprehensive and adequate care

for state sector patients is a provincial and national government priority, there needs to be an acknowledgement of further responsibility in ensuring comprehensive and adequate training for specialists. This should include reasonable access to all available agents, specifically where state facilities are designated training sites.

Christopher P. Szabo
Editor-in-Chief
South African Psychiatry Review

References

1. *Szabo CP. The Mental Health Care Act: challenges and opportunities. South African Psychiatry Review 2006; 9: 1-5.*
2. *Davis JM, Chen N, Glick ID. A meta-analysis of the efficacy of Second-Generation Antipsychotics. Archives of General Psychiatry 2003; 60: 553-564.*
3. *El-Sayeh HG, Morganti C, Adams CE. Aripiprazole for schizophrenia. Systematic Review. British Journal of Psychiatry 2006 ; 189, 102- 108.*
4. *Lieberman JA, Stroup TS, McEvoy J, Swartz M, Rosencheck R, Perkins D, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia: primary efficacy and safety outcomes of the Clinical Anitpsychotic Trials of Intervention Effectiveness (CATIE) Schizophrenia Trial. New England Journal of Medicine 2005; 353: 1209-1223.*
5. *Jones PB, Barnes TR, Davies L, Dunn G, Lloyd H, Hayhurst KP, et al. Randomized Controlled Trial of the Effect on Quality of Life of Second- vs First –Generation Antipyschotic drugs in Schizophrenia. Cost Utiltiy of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1). Archives of General Psychiatry 2006; 63: 1079-1087.*
6. *Lieberman JA. Comparative Effectiveness of Antipsychotic Drugs. A Commentary on Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1) and Clinical Trials of Intervention Effectiveness (CATIE). Archives of General Psychiatry 2006; 63: 1069-1072.*